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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/039,957	03/16/98	KORNBLITH	P 2509-970451

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1623	17

DATE MAILED: 08/01/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/039,957	Kornblith
Examiner	**Group Art Unit**
Ralph Gitomer	1623

☒ Responsive to communication(s) filed on *Jun 30, 1900*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1 and 23-32* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1 and 23-32* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

The CPA request and amendment received 6/30/00 have been entered and claims 1, 23-32 are currently pending in this application.

It is understood the present claims are directed to non-malignant cells and cells in general which includes malignant cells, whereas the claims of 08/679,056 and 09/095,993 are directed to malignant cells. As the function of the methods are identical, the method steps are identical, and the only difference is the state of the cells in the assay, the following rejection is made under obviousness double patenting.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 23-32 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of copending Application No. 09/095,993. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference in the claimed methods is the state of the cells being malignant or non-malignant.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 23-32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 5,728,541. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference in the claimed methods is the state of the cells. The claims of `541 are directed to malignant cells whereas the present claims are more broadly directed to cells in general.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23-32 are rejected under 35 U.S.C. 102(b) as being anticipated by each of Yen-Maguire, Stampfer, Morgan and Rotman.

Yen-Maguire (5,242,806) entitled "Method for Conducting the Cytotoxicity Assays on Tumor Cells" teaches in the abstract, assaying for the sensitivity of biopsied tumor cells to chemotherapeutic agents. In column 3 first full paragraph, measuring the responsiveness of multiple cell populations rather than single-cell suspensions. In column 3 lines 56-59, the requirement for single cell suspensions is eliminated. In column 10 lines 20-25, even if cells are seeded as aggregates, the cells will spread out.

Stampfer (4,423,145) entitled "Enhanced Growth Medium and Method for Culturing Human Mammary Epithelial Cells" teaches in column 3 under "Isolation of Epithelial Clumps," clumps of cells are obtained from a biopsy and then cultured. In column 6 last full paragraph, adriamycin sensitivity to specimens are determined with varying concentrations.

Morgan (5,270,172) entitled "Method to Predict Tumor Response to Therapy" teaches in column 5 Example 1, cancer tissue obtained is minced into fragments and cultured. In column 13 last full paragraph, chemotherapeutic drugs and doses are assayed.

Rotman (4,937,187) entitled "Methods for Separating Malignant Cells From Clinical Specimens" teaches in column 8 in the claims generally and claim 19 specifically, forming clumps of cells from tumor biopsies, establishing a cell culture, exposing the cell culture to a therapeutic agent and determining the sensitivity of the cells to the agent.

It would appear the inventive step is to not disaggregate a biopsy specimen into individual cells before plating but to plate clumps of cells prior to determining chemotherapeutic sensitivity. However, this is not claimed as the present claims are written in open-ended "comprising" terminology which does not exclude disaggregating the specimen. Mechanically separating as has now been added to the claims is clearly shown in all of the above references where biopsying itself is a method of mechanically separating. Further, a specimen from ascites or effusion fluid would not appear to be readily minced and would be encompassed by each of the above references.

Applicant's arguments filed 8/18/99 have been fully considered but they are not persuasive.

Applicant argues that Yen-Maguire may further process the cells to disaggregate them. Stampfer does not mechanically separate the cells. Morgan does not describe passaging a monolayer derived from the particulates but a suspension instead. Rotman also does not describe passaging a monolayer derived from the particulates.

It is the examiner's position that the claims do not exclude further processing to disaggregate cells because they are written in open-ended ‘comprising’ terminology. Stampfer inherently mechanically separates cells, see column 3 lines 14-20 where samples are prepared by gently lacerating the remaining tissue with opposing scalpels after additional dissection. The present claims are not directed to passaging a monolayer. Morgan in Example I columns 5-6 teaches a thin layer of cells on a slide is grown. Tissue culture monolayer is well known in this art and would have the expected function. In Rotman, see the abstract where fragments from biopsy sample can be prepared by mechanical dissociation.

The examiner requests applicant to specifically point out written description in the specification as originally filed for each of the features of new claims 25-32.

Claims 1, 23-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The newly added limitation directed to non-malignant cells and cells in general is not enabled. On page 6 first full paragraph of the present specification, applications of the invention are discussed including screening process for treatment or therapeutic agents for nonmalignant syndromes and psoriasis or wound healing agents as examples are disclosed. The claims are directed to assessing chemosensitivity of non-malignant cells, a method for identifying chemosensitivity of cells, and a method for identifying secreted cellular antigens produced by cells. The specification as originally filed does not provide a written description nor enable one of skill in this art how to assess chemosensitivity of non-malignant cells, identify chemosensitivity of cells nor identify any secreted cellular antigens produced by cells. No results of any of these processes are disclosed, and particularly no non-malignant cells are shown. It is understood psoriasis is not a malignant condition but nowhere is it set forth in the specification what the sensitivity of cells associated with psoriasis are chemosensitive to, how one would identify that sensitivity or any antigens produced by those cells. No results of any kind are seen.

Claims 1, 23-32 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1(e) sites are treated with treating means which is not related to chemosensitivity, no determining takes place before and after treating, and correlating chemosensitivity occurs which is not understood. What the control is or controls is not recited. More standard method steps include contacting, determining, correlating. The preamble of claim 23 is directed to assessing chemosensitivity of cells but the claim lacks any such step. In claim 23(a) ▒cells ascites▒ is queried. More importantly, how cells ascites or effusion fluid would be minced is not seen in view of the point of novelty being the particle size distribution. In claim 23(c) ▒said cohesive▒ lacks antecedent basis. In claim 23(e) what is correlated with what is not set forth. In claim 24 and all occurrences ▒active agent▒ lacks antecedent basis and is not understood as to what activity is intended. In claim 4 how the assessment takes place is indefinite and it is not seen how one could determine optimal sensitivity to a single agent in the presence of many agents. Further, no assessing takes place. In claim 26 ▒the process▒ lacks antecedent basis.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm. The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist can be reached on (703) 308-1701. The fax phone number for this Art Unit is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1234.

Ralph Gitomer
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